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Screening for Hearing Loss in Early Childhood Using Otoacoustic Emissions: Implications for Primary Care Physicians

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ABSTRACT

Objective. Given that permanent hearing loss is the most common birth defect, that a significant number of infants are lost to follow-up after newborn hearing screening, and that the incidence of hearing loss increases during childhood, primary care physicians are becoming increasingly aware of the importance of detecting hearing loss during a child's language learning years. Tympanometry and pneumatic otoscopy provide valuable information on middle ear health, but until recently no objective tool has been available to help primary care providers screen young children for permanent hearing loss. The objective of this study was to screen children 0 – 3 years of age for hearing loss using Otoacoustic Emissions (OAE) technology and to systematically document the screening and diagnostic outcomes.

Methods. A total of 4518 children, 0 - 3 years of age, in 4 states were screened by trained lay screeners using portable OAE equipment set to deliver stimuli and measurement levels sensitive to hearing loss as low as 25 decibels (dB) hearing level. The screening and follow-up protocol specified that children not passing the multi-step OAE screening be evaluated by local physicians and hearing specialists. Screening and diagnostic outcome data were systematically collected and analyzed.

Results. Of the 4518 children screened as a part of the study, 6% ultimately required medical or audiological follow-up. One hundred and seven children were identified as having a hearing loss or disorder of the outer, middle or inner ear requiring treatment or monitoring. Of these 107, 7 had permanent bilateral or unilateral hearing loss and included children who had passed the newborn screen, had referred but received no follow up, or were not screened at birth.

Conclusions. An objective screening tool, OAE technology holds great promise for pediatric primary care providers in reliably screening infants and toddlers for hearing loss during the critical language-learning years. As individual practitioners make decisions about how to meet children's hearing-health needs, and as professional organizations make broader recommendations on how and when periodic hearing screening should be conducted, the implementation of objective hearing screening methods during early childhood should be strongly considered.

BACKGROUND

Hearing loss is the single most common birth defect occurring at nearly double the combined incidence of Down Syndrome, Spina Bifida, and phenylketonuria. Language deficits from undetected and untreated hearing loss can result in illiteracy, educational under-achievement, and poor socialization.[1] Advances in technology and implementation of statewide newborn hearing screening programs over the past decade have raised the percentage of newborns screened in the United States from 3% to over 90%.[2] However, follow-up has been less comprehensive in many states with only about 50% of infants who are referred for medical or audiological follow-up receiving timely assessment or intervention.[3] It is estimated that by school age new cases of permanent hearing loss occur in approximately 6 per 1000 children in addition to the 3 per 1000 likely to be detected at birth.[4] Further, an estimated 35% of pre-school children experience repeated episodes of ear infections and intermittent hearing loss, some untreated for extended periods[5]. Although newborn screening has done much to improve detection of permanent hearing loss,[6,7] children not screened at birth, lost to follow-up, or presenting with post-neonatal hearing loss may still be picked up too late to prevent serious developmental problems associated with untreated hearing loss.[8]

Pediatricians have routinely utilized otoscopy, pneumatic otoscopy or tympanometry to diagnose common middle-ear disorders, but have had to rely on subjective methods such as observations of the child's behavioral response to sound (i.e. hand clapping or bell ringing) or parent perceptions of the child's behavior, to assess inner ear functioning of children 0 – 3 years of age. Otoacoustic Emissions (OAE) screening, used widely in newborn hearing screening programs, holds great promise for primary care providers in screening infants and toddlers for permanent hearing loss because it is: a) objective and independent of child's behavior; b) painless; c) portable, reliable and efficient; and d) simple to administer with an appropriate protocol.[9]

Given that permanent hearing loss is the most common birth defect, that a significant number of infants are lost to follow-up after newborn hearing screening, and that the incidence of hearing loss increases during childhood, primary care providers and professional organizations are becoming increasingly aware of the importance of hearing screening during a child's language learning years. Concurring with recommendations by the American Academy of Pediatrics promoting periodic screening in early and middle childhood,[10] authors of one multi-center study that followed screened infants to 9 months of age noted the need for subsequent screening in early childhood.[11] In that study, 22% of infants passing the newborn screen in some programs were shown to have permanent hearing loss. However, consensus on specific tests, equipment, protocols and populations (e.g., pre-school, well-baby, and high-risk infants) has yet to be reached. At present, the use of OAE technology has been increasing in clinical settings, but remains limited as the preponderance of attention has focused on newborn screening.[12]

The objective of this study was to screen children 0 – 3 years of age for hearing loss using Otoacoustic Emissions (OAE) technology and to systematically document the screening and diagnostic outcomes. Study data will begin to fill gaps in the current knowledge base related to objective, periodic hearing screening during early childhood and thereby help to inform hearing screening practices.

METHODS

Subjects

A total of 4518 children, 0 - 3 years of age, across Kansas, Oregon, Utah and Washington participated in the study. As part of Head Start requirements, all enrolled children must receive some type of hearing screening annually in conjunction with other health screenings. This allowed researchers to implement a standardized screening and follow-up protocol across 65 sites. Table 1 summarizes the demographic backgrounds of the children. Hearing screenings were conducted by lay screeners who attended a 6-hour training session and also had regular access to audiological technical support.

OAE Hearing Screening Methodology

OAE is a non-invasive procedure that generates an objective response from the inner ear. During OAE screening, the screener places a small probe into the ear canal that delivers a quiet tone or clicking sound and is also fitted with a sensitive receiving microphone. In a healthy ear, sound stimuli are transmitted through the middle ear to the inner ear where outer hair cells of the cochlea respond by producing an emission sometimes described as an "echo." This emission is picked up by the microphone, analyzed by the screening unit, and a "pass" or "refer" result is displayed on the unit's screen.[13] The ear will not pass the screening if there is: a) a blockage in the ear canal; b) a structural problem or excess fluid in the middle ear that interferes with hearing; or c) an impaired cochlea that is not responding normally to sound. A single type of OAE equipment was used in all sites set to deliver stimuli and measurement levels that are sensitive to hearing loss as low as 25 decibels (dB) hearing level.

In two large-scale studies of OAE screening, sensitivity was found to be 85%[14] and 100% [15] with specificity of 95% in both studies. Additionally, in a small-scale study of 110 children age 6 months to 15 years recovering from meningitis, OAE screening was found to be highly sensitive (100%) and reasonably specific (91%).[16]

Hearing Screening Protocol and Variables

Standardized procedures and manuals were used to train all screeners in performing OAE screening and adhering to an appropriate follow-up protocol. [17] Key components of the protocol included a visual inspection of the ear and up to three OAE screenings over a 2 – 4 week period. [18] Because the protocol required that children not passing the initial OAE screening be screened up to two more times before receiving an

evaluation, the protocol was designed to significantly limit false positive findings. The screening and follow-up protocol specified that children not passing the multi-step OAE screening be evaluated by a health care provider, and, as needed, by a pediatric audiologist. Key data included:

Visual Inspections: 1) Pass, no observable abnormalities, or; 2) Refer, an observable abnormality.

OAE Screening Outcomes: 1) Pass; 2) Can't test, generally due to child's excessive movement or distress; or 3) Refer, possible hearing loss.

Diagnostic Outcomes: Diagnoses of hearing health conditions were made by health care providers and audiologists in the communities where children were located.

RESULTS

Based on the multi-step screening protocol, 257 of 4518 (6%) children screened required medical or audiological follow-up. As shown in Table 2, 107 of the 159 (67%) children who needed and received diagnostic follow-up were identified with a hearing loss or disorder requiring treatment or monitoring. A breakdown of these 107 cases revealed that 7 children had permanent hearing loss; 83 had otitis media; 2 had occluded pressure equalization tubes; and 15 had excessive earwax or congestion.

The remaining 52 of the 159 receiving follow-up were diagnosed as normal and no further treatment was recommended. It is probable that some of these cases initially had a condition that resolved by the time of diagnostic examination although the potential for false positives also exists. Finally, 98 of the 257 children (38%) needing diagnostic follow-up after the OAE screening exited the Head Start program before this was completed. Their diagnostic status remains unknown.

As a result of the OAE screening and follow-up assessment, 7 of 4518 (1.5 per 1000) children who were screened were found to have a permanent hearing loss. Table 3 summarizes additional information about these 7 children with detected permanent hearing loss, including type of hearing loss, age at diagnosis and newborn screening results. Four of the children had a permanent sensorineural hearing loss (originating in the cochlea) while 3 had a permanent conductive loss (originating in the middle ear).

Protocol Evaluation

Data from this 36-month screening project were coded and analyzed to evaluate the multi-step screening and follow-up process to determine if the goals of the protocol were met. The median time for a single screening was 4.0 minutes (mean of 4.8 minutes) with a range from 1 to 30 minutes.

Visual Inspection Outcomes. The first step in the screening process was the visual inspection of the outer ear for abnormalities or obvious indicators of active ear infection. If anomalies were noted, the next step was a medical evaluation. Eight children (< 1%) did not pass the visual inspection and required direct medical follow-up.

OAE Screen 1 Outcomes. The 4510 (>99%) children passing the visual inspection were then screened using OAE equipment. Of the 4510 children receiving an initial OAE screening, 3412 (76%) passed and required no further follow-up. A total of 809 (18%) "failed" or "referred" on this first screening, while 290 (6%) were documented as "can't test" (generally because children were uncooperative on that day). Thus, a total of 1099 (24%) children did not pass the initial OAE screening. Although the screening protocol specified that children not passing the initial screening should typically receive a subsequent OAE screening before receiving medical or audiological evaluation, screeners were instructed to exercise their own judgment in directly initiating a medical evaluation if circumstances warranted (e.g., if a child had a known history of ear infection, parents voiced concern about the child's hearing, etc.) Thus, of the 1099 children who did not pass this initial OAE screening, 44 (4%) were determined to need direct evaluation by a health care provider on the basis of these types of additional concerns.

OAE Screen 2 Outcomes. Of the 1055 children needing a second screening, 502 (48%) passed and required no further follow-up. A total of 295 (28%) "failed" or "referred" on the screening and 104 (10%) could not be tested. The remaining 154 (15%), however, did not receive this second screening due to the Head Start program closing for the year/season or the child exiting the program. Of the 399 children who did not pass this second OAE screening, 40 (10%) were determined to need direct evaluation by a health care provider due to additional concerns.

OAE Screen 3 Outcomes. Of the 359 children needing and available for a third screening, 123 (34%) passed and required no further follow-up. A total of 135 (38%) "failed" or "referred" on the screening and 30 (8%) could not be tested. The remaining 71 (20%) however, did not receive this third screening due to the Head Start program closing for the year/season or the child exiting program. Thus, 165 children were identified as needing medical evaluation after the third screening.

Medical or Audiological Follow-up Outcomes. A total of 257 (6%) of 4518 children in the study required medical or audiological follow-up: 8 after Visual Inspection, 44 after OAE Screen 1, and 40 after OAE Screen 2, as well as those not passing after completing all three steps of the screening process (n=165). As described in Table 2, 107 (42%) of the 257 children were found to have a hearing loss or disorder while 52 (20%) were determined to have "normal" hearing. The remaining 98 children (38%) exited the Head Start program, or the program closed, before the diagnostic follow-up could be conducted.

Taken together, these data can be used to calculate the specificity of the three-step screening protocol used in this study. Of the 4510 children who were screened, 4420 either passed the screen (n=4261) or had evaluation data available at the completion of the process (n=159). Of the 159 children with evaluation data, 52 had normal hearing and 107 had a hearing problem. Following standard definitions for evaluating screening tests[19], there were 107 true positives (2.4%), 52 false positives (1.2%), and 4261 true negatives (96.4%); the specificity of the screening test (true negatives ÷ [true negatives + false positives]) was 98.8%, and the positive predictive value (true positives ÷ [true positives + false positives] was 67.3%.

DISCUSSION

This study showed that OAE screening led to the identification of children who were ultimately diagnosed with a wide range of hearing-health conditions warranting monitoring and treatment. The 6% fail/refer rate compares favorably with rates reported by effective hospital-based newborn hearing screening programs.[20] The fail/refer rate for infants and toddlers is expected to be higher than newborns given transient conditions that are more prevalent in this population. The specificity of 98.8% and the positive predictive value of 67.3% indicate that over-referral was not occurring. The positive predictive value represents a conservative estimate due to the high probability of outer and middle ear conditions that can resolve prior to a clinical diagnostic visit.

As a result of the OAE screening conducted in this study, 7 children with permanent hearing loss were identified who were either not screened at birth, were screened and subsequently lost to follow-up after hospital discharge, or who passed the newborn hearing screen but presented with post-neonatal hearing loss. As a result of the identification through screening and follow-up, these children were connected with audiological services, local early intervention services, and family support programs.

The cases detected in this screening program demonstrate common problems in child hearing health that merit further discussion. Case #1 is a child who did not pass the newborn hearing screening and who did not receive follow-up from health-care providers or audiologists. Loss to follow-up from newborn hearing screening is significant in some states--as high as 50% of infants who need follow-up.[3]

Cases #2, #5, and #6 are children with probable post-neonatal hearing loss. Despite passing the hearing screening at birth, these children referred on OAE screening by 15 to 30 months of age. Although hearing loss was then diagnosed as mild/moderate, and in two cases unilateral, hearing loss among young children often deteriorates over time.[21] Although there has been no single definitive study of the rate of post-natal hearing loss, the literature indicates that from11% to 50% of all cases of permanent hearing loss are likely post-natal.[22]

Finally, Cases #3, #4, and #7 illustrate that periodic screening is important since some children were not screened at birth or their newborn screening status could not be verified. It is possible but unknown at this time if these cases were congenital.

The value of using OAE equipment to screen children for permanent hearing loss after fluctuating middle ear conditions have been resolved is also highlighted by these cases. Three of the 7 children were diagnosed with permanent sensorineural hearing loss in addition to otitis media. Parents and community-based hearing screening programs often assume, incorrectly, that primary care providers have the capacity to objectively screen for permanent hearing loss. The reality is that while physicians regularly diagnose and treat fluctuating middle ear conditions, very few are equipped to screen cochlear functioning or to detect permanent hearing loss in children 0 – 3 years of age.

Finally, of the 7 children identified with permanent hearing loss, 5 were diagnosed as having a bilateral loss while 2 had unilateral loss. The importance of unilateral hearing loss tends to be under-appreciated as it is not considered disabling. However, unilateral loss is associated with progressive declines that can affect the other ear.[23] Children with unilateral hearing loss often respond to sound in a way that would indicate they are hearing, particularly in one-on-one interactions, which makes unilateral loss especially difficult to identify using subjective methods. Both unilateral and mild hearing losses often go unidentified until children are in school when language and academic delays are apparent.[24, 25]

In addition to the 7 children identified with permanent hearing loss, 100 other children in the study were diagnosed with hearing problems–primarily otitis media (n=85) including two with occluded PE tubes. Although there is professional debate on the effect that otitis media may have on language development and on what constitutes optimal intervention,[26, 27] the OAE hearing screening process was valuable in helping to identify children with compromised hearing health who needed further monitoring or treatment.

Unfortunately, 98 children who did not pass the multi-step OAE screening process exited the Head Start program before a diagnostic evaluation could be completed. Of the 159 children who were referred for and received a diagnostic evaluation, 107 (67%) were diagnosed with a hearing disorder. Using this percentage to extrapolate to the 98 children who exited, it can be estimated that 66 of the 98 had a hearing loss or disorder and that approximately 4 of those 98 may have had a permanent hearing loss. Given the 7 cases detected and a potential 4 additional cases from those who exited the program, the data suggest that the use of OAE screening during early childhood would result in 2.4 per 1000 newly detected cases of permanent hearing loss in addition to the 3 per 1000 expected from newborn screening.[28] While this data provides an estimate of the magnitude of the problem, larger-scale studies in which loss to follow-up is minimized are needed to measure the true incidence of childhood hearing loss.

Whether working in community clinics, private practice settings, or serving as the medical home for children enrolled in early childhood programs, physicians play a crucial role in hearing detection and intervention efforts. They are also in a key position to refer children for audiological evaluation and early intervention services. Although studies are beginning to explore the value of incorporating OAE screening during well-child visits, larger-scale studies and formal data collection are needed to explore implementation issues such as optimal screening and follow-up protocols and the effectiveness of training materials in health care settings.[29]

The results of this study demonstrate that OAE technology, when used with an appropriate screening and follow-up protocol, can make a valuable contribution by identifying hearing loss that can potentially disrupt language acquisition, literacy, socialization and overall school readiness. An objective screening tool, OAE technology holds great promise for pediatric health care providers in reliably screening infants and toddlers for hearing loss during the critical language-learning years. As individual

practitioners make decisions about how to meet children's hearing-health needs, and as professional organizations make broader recommendations on how and when periodic hearing screening should be conducted, the implementation of objective hearing screening techniques during early childhood should be considered.

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Table 1. Demographic Characteristics of 4518 OAE Screened Children

Gender	
• **Female**	**2107 (47%)**
• **Male**	**2347 (52%)**
• **Unknown**	**64 (1%)**
Age (months) **Mean= 22 SD=(13)**	
• **0-12**	**1119 (25%)**
• **13-24**	**1084 (24%)**
• **25-36**	**1453 (32%)**
• **36-48**	**862 (19%)**
Type of Program	
• **Migrant Head Start**	**2049 (46%**
• **Early Head Start**	**2225 (49%)**
• **American Indian Head Start**	**244 (5%)**
Ethnicity	
• **Hispanic**	**2437 (54%)**
• **Caucasian**	**1331 (29%)**
• **American Indian**	**271 (6%)**
• **African American**	**158 (4%)**
• **Bi-racial**	**98 (2%)**
• **Asian**	**21 (1%)**
• **Unknown**	**202 (4%)**

Table 2. Summary of Diagnostic Outcomes among 257 Referred from Screening

Diagnostic Outcomes	**Number of Children**
Hearing loss or disorder requiring treatment or monitoring	**107 (42%)**
Permanent hearing loss	7
Otitis media (ear infection)	83
Occluded pressure equalization (PE) tubes	2
Excessive earwax or congestion	15
No treatment recommended	**52 (20%)**
Exited before diagnosis completed/referral appointment completed	**98 (38%)**
Total	**n=257**

Table 3. Information on Children Identified With Permanent Hearing Loss

Case	Diagnosis and Age at Diagnosis	Newborn Hearing Screening Results
1	Bilateral, severe sensorineural loss and Otitis Media (9 months)	Referred; subsequently lost to follow-up
2	Bilateral, severe conductive loss (2-1/2 years)	Passed
3	Bilateral, mild/moderate conductive loss and Otitis Media (3 years)	Not screened at birth
4	Bilateral, mild/moderate conductive loss (2 years)	Not born in U.S., not screened at birth
5	Unilateral, mild/moderate sensorineural loss in left ear (15 months)	Passed
6	Unilateral, mild/moderate high frequency sensorineural loss in left ear (2 years)	Passed
7	Bilateral, severe, sensorineural loss and Otitis Media (2-1/2 years)	Unknown, unconfirmed verbal history